DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 7, 2014

MetriTrack, LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K141870
Trade/Device Name: Breast Volume Navigator
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO
Dated: July 29, 2014
Received: July 30, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141870

Device Name
Breast Volume Navigator (BVN)

Indications for Use *(Describe)*

The Breast Volume Navigator (BVN) is an add-on accessory for existing ultrasound imaging systems, and is intended to control position and movement of ultrasound transducers for the systematic acquisition of 2 dimensional image slices throughout a volume of interest. The BVN is intended to acquire, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional image processing.

The BVN will allow exporting to any third party application that has the appropriate level of DICOM compliance.

The BVN is intended as a general purpose digital 3D breast ultrasound image processing tool for radiology and surgery.

The BVN is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of a patient's breast when used with an automatic scanning linear array transducer.

The device is not intended to be used as a replacement for screening mammography.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

MetriTrack

510(k) SUMMARY

Breast Volume Navigator (BVN™)

510(K) Number: **K141870**

Submitter's Name: MetriTrack, LLC

Address:
4415 W. Harrison Street
Suite 230
Hillside, IL 60162

Telephone Number: (708) 498-3578

Contact Person: Mirela Wohlford

Date Prepared: July 28, 2014

Name of Device: Breast Volume Navigator (BVN™)

Address of Sponsor:
MetriTrack, LLC
4415 W. Harrison Street
Suite 230
Hillside, IL 60162

Common or Usual Name: System, Imaging, Pulsed Echo, Ultrasonic

Regulation Number: 21 CFR 892.1560

Product Code: IYO

Device Class: Class II

Predicate Devices:

TomTec Digital Ultrasound Image Analysis System (K963807)
Acuson 3D Organ Assessment with Magnetic Position Sensing (K002807)
U-Systems ABUS Diagnostic Ultrasound System (K052355)

MetriTrack

510(k) SUMMARY

Breast Volume Navigator (BVN™)

510(K) Number: **K141870**

Intended Use / Indications for Use:

The Breast Volume Navigator (BVN) is an add-on accessory for existing ultrasound imaging systems, and is intended to control position and movement of ultrasound transducers for the systematic acquisition of 2 dimensional image slices throughout a volume of interest. The BVN is intended to acquire, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional image processing.

The BVN will allow exporting to any third party application that has the appropriate level of DICOM compliance.

The BVN is intended as a general purpose digital 3D breast ultrasound image processing tool for radiology and surgery.

The BVN is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of a patient's breast when used with an automatic scanning linear array transducer.

The device is not intended to be used as a replacement for screening mammography.

Technological Characteristics

The Breast Volume Navigator (BVN) System comprises hardware components and a software element, including the following components: a magnetic position tracking device, sensor attaching pieces used to attach the magnetic sensors to the skin and ultrasound probe, a central control unit, and software for controlling the system, collecting and processing images and positional data, and performing automated annotation.

The Breast Volume Navigator (BVN) has a touch-screen user interface and a push-button for power on the system. The User Interface can be placed on a stand next to the examination table for ease of use and ergonomic adaptation.

The BVN has a USB port available for transferring data files via USB Memory Stick. The BVN has an Ethernet port for connection to a PACS system, using DICOM. The BVN has a VGA/DVI Input Ports for capturing images from an ultrasound imaging scanner.

MetriTrack

510(k) SUMMARY

Breast Volume Navigator (BVN™)

510(K) Number: **K141870**

The Breast Volume Navigator (BVN) System receives ultrasound DICOM images from the US machine via the network connection and telemetry data from a position tracking system.

The BVN automatically detects when the image is being frozen on the US machine and takes a snapshot of the telemetry data at that time. Later, when the BVN receives the DICOM image, it associates the telemetry data to the image from the time when the image was frozen on the US machine.

The customer's existing ultrasound probe securely attaches to the BVN probe sensor. During a scan, the operator applies constant pressure to the transducer against the patient's breast tissue and can rotate the transducer (pitch and roll) to accommodate for the physical characteristics of the breast.

Exam data is subsequently reviewed on standard radiological viewing stations. Any lesions or anomalies discovered during the review process can be evaluated using the localization and measurement tools included in the software.

Pursuant to 809.92(a)(6), MetriTrack, LLC claims that the Breast Volume Navigator (BVN) system is substantially equivalent to the devices previously cleared by FDA in K963807, K002807 and K052355. MetriTrack, LLC claims this equivalence because the proposed device has an equivalent intended use, manufacturing materials, operating principles, and physical and operational specifications compared to the predicate devices.

The applicant's device (Breast Volume Navigator) and the predicated devices listed above are accessories to an Ultrasonic Pulsed Echo Imaging System that have a Moderate Level of Concern.

The MetriTrack Breast Volume Navigator Software Application is Safety Class B according to ANSI/AAMI/IEC 62304: 2006. Determination of the LOC and Safety Class is the result of risk assessment activities per ISO 14971.

Further, MetriTrack, LLC has determined that its device advances the field without deviating from the scope and spirit of the Act by enabling the user to visualize the ultrasound probe position and orientation over the patient's breast diagram in real time and perform automatic annotation in a stand-alone device that works with any standard ultrasound imaging system which have been previously cleared by FDA under the 510(k) process.

MetriTrack

510(k) SUMMARY

Breast Volume Navigator (BVN™)

510(K) Number: **K141870**

SUBSTANTIAL EQUIVALENCE CHART

Substantial Equivalence Parameters		MetriTrack - Breast Volume Navigator (BVN™)	TomTec - Digital Ultrasound Image Analysis System	Acuson - 3D Organ Assessment with Magnetic Position Sensing	U-Systems – ABUS Diagnostic Ultrasound System
Indications for Use	Use together with a medical ultrasound scanner	Yes	Yes	Yes	Yes
	Intended to control position and movement of ultrasound transducers for the systematic acquisition of 2 dimensional image slices throughout a volume of interest	Yes	Yes	No	Yes
	Collecting 3D data during ultrasound scanning	Yes	Yes	Yes	Yes
	Apply collected 3D data in later image processing	Yes	Yes	Yes	Yes
	The BVN will allow exporting to any third party application that has the appropriate level of DICOM compliance.	Yes	No	Yes	No
	The BVN is intended as a general purpose digital 3D breast ultrasound image processing tool for radiology and surgery.	Yes	Yes	Yes	Yes
	The device is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of a patient's breast when used with an automatic scanning linear array transducer.	Yes	No	No	Yes
Patient Population		This System is intended to	Anyone needs an	Anyone needs an	This System is intended to

510(k) SUMMARY

Breast Volume Navigator (BVN™)

510(K) Number: **K141870**

Substantial Equivalence Parameters	MetriTrack - Breast Volume Navigator (BVN™)	TomTec - Digital Ultrasound Image Analysis System	Acuson - 3D Organ Assessment with Magnetic Position Sensing	U-Systems – ABUS Diagnostic Ultrasound System
	be used on primarily women patients.	ultrasound examination for an internal organ including breast.	ultrasound examination for an internal organ including breast.	be used on primarily women patients.
Design	Using a magnetic position sensing unit to collect 3D spatial position information.	The Device is a high performance computer system based on Intel motherboard and Microsoft DOS/Windows standards and it incorporates a proprietary image digitizer circuit board and proprietary software for the acquisition, analysis, storage and retrieval of 3D ultrasound	Using a magnetic position sensing unit to collect 3D spatial position information.	Automated control of custom B Mode ultrasound probe during the scan. Probe scanner located on breast with articulating arm.

510(k) SUMMARY

Breast Volume Navigator (BVN™)

510(K) Number: **K141870**

Substantial Equivalence Parameters	MetriTrack - Breast Volume Navigator (BVN™)	TomTec - Digital Ultrasound Image Analysis System	Acuson - 3D Organ Assessment with Magnetic Position Sensing	U-Systems – ABUS Diagnostic Ultrasound System
		image data sets.		
Where Used	Clinical Radiology Department, Physicians' offices for ultrasound examination	Same	Same	Same
End User	Qualified medical imaging personnel that are familiar with traditional breast ultrasound procedures and techniques.	Same	Same	Same

Electrical Testing

EMC testing per IEC 60601-1-2, Edition 3.0 Issued: March 2007 and Electrical Safety Testing per IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) were performed for the Breast Volume Navigator. All test results were acceptable for the Breast Volume Navigator.

Performance Data

Performance, Verification and Validation testing for the Breast Volume Navigator was performed per internal procedures, which are compliant with 21 CFR Part 820.30, to ensure that all functional requirements have been met, and that core functions execute as expected.

MetriTrack

510(k) SUMMARY

Breast Volume Navigator (BVN™)

510(K) Number: **K141870**

Testing was conducted in-house by trained personnel in a simulated work-environment using phantoms to obtain the functional, accuracy and precision test results.
DESIGN VERIFICATION TEST: The design specifications of the Breast Volume Navigator (BVN) system were tested and verified to confirm that the product performance fulfilled those specification requirements.
DESIGN VALIDATION TESTS – NON-CLINICAL TESTING: System Validation Testing was performed on a test phantom with 9 test locations in 4 layers above the test phantom, these layers were intended to cover the height of the operative volume, which is 35cm. In this environment the BVN system has achieved the following:

- Accuracy and Precision of 5 mm for measuring the distance of a target.
- Accuracy and Precision of 5 degrees for measuring the Clock Face Angle of a target.
- Accuracy of 5 degrees for measuring the angles of the test phantom relative to the examination bed in different anatomical planes, i.e. Coronal, Transverse, and Sagittal planes.

Substantial Equivalence

The **Breast Volume Navigator** is as safe and effective as the predicated devices: TomTec Digital Ultrasound Image Analysis System (K963807), Acuson 3D Organ Assessment with Magnetic Position Sensing (K002807), and U-Systems ABUS Diagnostic Ultrasound System (K052355). The **Breast Volume Navigator** has the same indicated uses and similar indications, technological characteristics, and principles of operations as its predicate devices. The minor technological differences between the **Breast Volume Navigator** and its predicate devices raise no new issues of safety and effectiveness.
Performance data demonstrate that the **Breast Volume Navigator** is as safe and effective as its predicate devices. Thus, the **Breast Volume Navigator** is substantially equivalent.